



medical creative
technologies, inc.

K954824

EXHIBIT 3

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510(k) SUMMARY

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Name of Contact Person: Perk Crook

October 20, 1995
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Trade Name: **PROTECTOR® Retractor and
PROTECTOR® Retractor with Drape**

Common Name: **PROTECTOR® Retractor**

Classification Name: Protector, Wound, Plastic

Classification Number: 79EYS

The legally marketed devices to which we are claiming equivalency are a wound edge protector drape and a self-retaining retractor.

Description of the Device:

The **PROTECTOR® Retractor** is a sterile, disposable device. The **PROTECTOR® Retractor** consists of an open-ended cylinder with a flexible o-ring at each end. The **PROTECTOR® Retractor with a drape** is the same configuration, except that it has a drape that is an integral part of it.

Intended Use of the Device:

This device is to be used to protect and retract an incision in the abdominal wall. This is accomplished by placing one o-ring through the incision into the peritoneum cavity while the other o-ring remains outside of the incision. The outside o-ring is then rolled down against the skin. This lines the wound to protect against contamination and holds the incision open.

Developers of innovative medical devices

Summary of Technical Characteristics of this Device Compared to the Predicate Device:

The **PROTECTOR®** Retractor accomplishes what the "Wound Edge Protector Drape" and "Self-Retaining Retractors" accomplish, except that it is one device rather than two. The "Wound Edge Protector Drape" is made out of the same type of material as the **PROTECTOR®** Retractor, whereas the "Self-Retaining Retractor" is made out of stainless steel and is an assembly of various angled irons, rods, clamps and screws. The **PROTECTOR®** Retractor accomplishes the same thing as the "Wound Edge Protector Drape" and "Self-Retaining Retractor" used in concert. The **PROTECTOR®** Retractor is a single-use disposable device as is the "Wound Edge Protector Drape", whereas the "Self-Retaining Retractor" is re-usable.

Assessment of Performance Data:

The **PROTECTOR®** Retractor was lab tested on a fake abdominal wall and in pig studies to verify that it could protect the wound at the same time as retracting the wound (holding it open). Both **PROTECTOR®** Retractor and the two predicate devices accomplished the same thing, except that the **PROTECTOR®** Retractor is much simpler to use and keeps the operating area clear of any contraptions.

Assessment of Performance Data- Clinical:

The **PROTECTOR®** Retractor is a component of the **DEXTERITY®** Pneumo Sleeve and **PROTECTOR®** Retractor which has been through a pilot clinical and is presently in a pivotal clinical. The results of the pilot clinical (41 subject) and the pivotal clinical to date is that the **PROTECTOR®** Retractor works safely and effectively to protect the wound and hold it open. The **PROTECTOR®** Retractor will be available in four different sizes which will accommodate different size incisions depending on the abdominal surgery being undertaken.

Conclusion Drawn from the Non-Clinical and Clinical Data:

It is concluded that the **PROTECTOR®** Retractor with or without Drape is as safe and effective as the two predicate devices from the standpoint of toxicology, protection of the wound and the physical retraction of the wound.

This concludes the summary for this 510(k).